

November 5, 2000

Dockets Management Branch  
The Food and Drug Administration  
Department of Health and Human Services, Rm. 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

Re: Docket Number: 99P-1340/CP 1  
Petition the FDA Have Calvin Klein's Eternity eau de parfum declared "misbranded"

Dear Sir or Madam:

I have recently learned that, in May, 1999, the Environmental Health Network (EHN) submitted a petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded.

I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10.

Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning--The safety of this product has not been determined."

As the petition shows, "Eternity" contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, epilepsy, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, care givers and teachers.

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I, myself, am keenly aware of the health effects of fragrance products. When I am exposed to such products, I can experience a variety of symptoms including:

- headache
- sneezing
- coughing
- chest discomfort, a lingering dull clod-like, tightness behind my sternum
- aching in chest
- nausea
- difficulty concentrating
- low back pain, extreme tension on the fascia of my sacrum, muscle tension
- irritability
- fatigue, sometimes extreme exhaustion
- flushing/redness of ears
- sudden, extreme appetite
- depression
- hyperactivity
- peripheral "lightness", feeling that the surface of my limbs is vapor

In times when exposures have been frequent, I have also experienced:

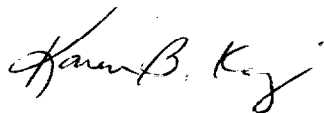
- tingling sensations in my muscles, like electricity moving rapidly through them
- a sensation of razor blades zipping through my body
- a sensation that a portion of my scalp was floating off of my head
- a "cave like" chest, as though my lungs were frozen open and become hard

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings.

These toxic chemicals act as powerful barriers to people with sensitivities. I battle daily to continue working while dodging products and enduring the questioning glances of the many people who remain ignorant of the facts. Your support of responsible labeling of these products will be truly appreciated.

Thank you.

Sincerely,

A handwritten signature in cursive script, appearing to read "Karen B. King".

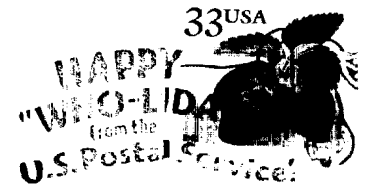
Karen B. King  
348 Hermosa Drive, NE  
Albuquerque, NM 87108

K King  
348 Hermosa Dr. NE.  
Albq., NM 87108

~~Rockville, MD 20857~~



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